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GCI-0017

Inventors:

Wunderink et al.

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## REMARKS

Claims 1-5 are pending in the instant application. The specification and the claims 1, 2 and 5 have been amended in accordance with the Examiner's requirement to include a Sequence Listing and SEQ ID NO: identifiers for the known human TNFα gene (SEQ ID NO:1) as set forth in GenBank Accession No: NM\_000594 and NCBI reference ID rs1800629 and the allelic variants, SEQ ID NO:2 and 3, as taught throughout the instant specification, for example at page 4, lines 16-20, page 4, line 31-33, and page 5, lines 5-13. Thus, no new matter has been added and entry is respectfully requested.

Claims 1-5 have been subjected to a Restriction Requirement as follows:

Group I, claim 1, drawn to a method of identifying a patient at an increased risk of death from community-acquired pneumonia; classified in class 435, subclass 6;

Group II, claim 2, drawn to a method of treating patients with a pneumococcal and/or influenza vaccine, classified in class 435, subclass 235.1;

Group III, claims 3-4, drawn to an agonist and method of screening to identify compounds which stimulate the action or

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synthesis of the TNFalpha polypeptide, classified in class 435, subclass 69.1;

Group IV, claims 3-4, drawn to an antagonists and methods of screening to identify compounds that inhibit the action or synthesis of the TNFalpha polypeptide, classified in class 435, subclass 69.1; and

Group V, drawn to a method of treating community-acquired pneumonia by administering an antagonist, classified in class 435, subclass 7.1. The Examiner has listed claims 23-25 in this Group. Since pending claims are only inclusive of claims 1-5, Applicants are assuming that this is a typographical error and that Group V was meant to include claim 5 only.

The Examiner suggests that these Groups are distinct from each other because their claims are drawn to methods that are both physically and functionally distinct and one method is not required for another method. The Examiner also suggests that the searches for the methods are not co-extensive and examination of the five methods in one patent application would result in undue burden.

Applicants respectfully traverse this Restriction Requirement.

MPEP §803 provides two criteria which must be met for a

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restriction requirement to be proper. The first is that the inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction is not required.

In the instant application, all claims relate to the finding that the A allele in the TNF $\alpha$  gene at the -308 locus is associated with increased risk of community-acquired pneumonia (CAP). Accordingly, a search relating to the A allele in the TNF $\alpha$  gene at the -308 locus will reveal all prior art relating to any of the claimed methods. Accordingly, Applicants believe that including all the claims in the instant application would not place an undue burden on the Examiner if the Restriction is not made.

Thus, since this Restriction Requirement does not meet both criteria as set forth in MPEP § 803 to be proper, reconsideration and withdrawal of this Restriction Requirement is respectfully requested.

However, in an earnest effort to be completely responsive, Applicants elect to prosecute Group I, claim 1, with traverse.

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Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Respectfully submitted,

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Date: August 25, 2003

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